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EXAM	
EXAMINER	
PHAN, HIEU	
ART UNIT	PAPER NUMBER
3738	
	ART UNIT

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application	No	Applicant(s)	<del>(/</del> 9
		140.		·
Office Action Summary	09/782,804		SIRHAN ET AL.	
Onice Action Summary	Examiner		Art Unit	
The MAILING DATE of this communical	Hieu Phan	over shoot with the	3738	Se
Period for Reply	uon appears on the c	over sneet with the c	on espondence addre	~-
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICA  - Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this communic  - If the period for reply specified above is less than thirty (30) da  - If NO period for reply is specified above, the maximum statuto  - Failure to reply within the set or extended period for reply wifl,  - Any reply received by the Office later than three months after the period for the provided period for the provided period for reply wifl,  - See 37 CFR 1.704(b).	ATION.  17 CFR 1.136(a). In no event cation.  ays, a reply within the statuto ory period will apply and will e. by statute. cause the application.	however, may a reply be tin ry minimum of thirty (30) day xpire SIX (6) MONTHS from tition to become ABANDONE	nety filed s will be considered timely. the mailing date of this comm D (35 U.S.C. § 133).	unication.
Status			•	
1) Responsive to communication(s) filed				
	)☐ This action is n			
3) Since this application is in condition for closed in accordance with the practice	or allowance except t e under <i>Ex parte Qua</i>	or formal matters, pl ayle, 1935 C.D. 11, 4	rosecution as to the n 153 O.G. 213.	ients is
Disposition of Claims			•	
4)⊠ Claim(s) <u>1-36,38-50 and 54-59</u> is/are p			•	
4a) Of the above claim(s) 1-36 is/are wi	ithdrawn from consid	leration.		
5)⊠ Claim(s) <u>54</u> is/are allowed.				
6)⊠ Claim(s) <u>38-50 and 55-59</u> is/are rejecte	ed.			
7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restrictio	on and/or election rec	juirement.		•
Application Papers	Vominer			
9) The specification is objected to by the E  10) The drawing(s) filed on is/are: a)		hiected to by the Exa	miner.	
Applicant may not request that any object				
11) The proposed drawing correction filed o				
If approved, corrected drawings are requi			·	
12) The oath or declaration is objected to by				
Priority under 35 U.S.C. §§ 119 and 120				
13) Acknowledgment is made of a claim fo	r foreign priority und	er 35 U.S.C. § 119(a	a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:		•		
1. Certified copies of the priority do	cuments have been	received.		
2. Certified copies of the priority do			ion No. <u>·      </u> .	
<ul> <li>3. Copies of the certified copies of application from the Internation</li> <li>* See the attached detailed Office action from the action from</li></ul>	ional Bureau (PCT F	tule 17.2(a)).		age
14) Acknowledgment is made of a claim for				oplication).
a)  The translation of the foreign langu 15)  Acknowledgment is made of a claim for	uage provisional app	lication has been re	ceived.	
15) Acknowledgment is made of a claim for Attachment(s)	domestic priority un	20, 00 0.0.0. 33 12	e enterer 1861	
1) Notice of References Cited (PTO-892)		4) Interview Summa	y (PTO-413) Paper No(s).	·
2) Notice of Praftsperson's Patent Drawing Review (PTC 3) Information Disclosure Statement(s) (PTO-1449) Paper	D-948)	5) Notice of Informat 6) Other:	Patent Application (PTO-1	52)

Application/Control Number: 09/782,804

Art Unit: 3738

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#### **Double Patenting**

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 54-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52-59, 61 and 62 of copending Application No. 09/782804. Although the conflicting claims are not identical, they are not patentably distinct from each other because method of using mizoribine and methylprednisolone to inhibit restenosis in a blood vessel following recanalization of the blood vessel.

# Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 09/782,804

Art Unit: 3738

4. Claims 42-44 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Harish et al. (U.S. Patent 6,506,437).

Harish et al. disclose vascular stent (10) coated with therapeutic agents, such as methylprednisolone and methotrexate as is claimed (Abstract, column 1 lines 15-38, column 2 lines 1-43, column 4 lines 10-20, column 6 lines 13-25 and 37-67 and column 7 lines 1-52).

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 38-41, 45-50 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (U.S. Patent 6,506,437).

Harish et al. is explained as before. Harish et al. fail to disclose the rate which the therapeutic agents are release from the stent as claimed in claims 38-41 and 56.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the rate which the therapeutic agents are release from the stent as claimed in claims 38-41 and 56, since it has been held that where the general conditions of claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Application/Control Number: 09/782,804 Page 4

Art Unit: 3738

## Allowable Subject Matter

7. Claim 54 is allowed.

# Response to Arguments

8. Applicant's arguments with respect to claims 38-50 and 55-59 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3738

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Hieu Phan Examiner Art Unit 3738

CORRINE McDERMOTT SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700